8-19-94

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: The HED Chapter of the Reregistration Eligibility Decision Document (RED) for Linuron

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From: John C. Redden, M.S.
Chemical Coordination Branch
Health Effects Division (7509C) 8/12/94

Thru: Debra Edwards, Chief
Chemistry Coordination Branch
Health Effects Division (7509C) Debra Edwards 8/17/94
and

Richard D. Schmitt, Ph.D., Acting-Director
Health Effects Division (7509C) Richard D Schmitt 8/19/94

To: Esther Saito, Chief
Reregistration Branch
Special Review and Reregistration Division (7508W)

Please find attached the Human Health Assessment for the Linuron Reregistration Eligibility Decision Document (RED). This chapter includes the Hazard Assessment from S. Makris in TBII (ATTACHMENT I), the Occupational/Residential Exposure Assessment from J. Evans in OREB) (ATTACHMENT II), the Product and Residue Chemistry Assessments from D. McNeilly in CBRS (ATTACHMENT III), and the Dietary Risk Analysis from J. Kariya in SAB (ATTACHMENT IV).

A tolerance reassessment was provided by CBRS and may be found on pp. 21-26 of the CBRS chapter. No Codex MRLs have been established; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

Linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea] is a substituted urea herbicide, used to control germinating and newly emerging grasses and broad-leaved weeds, registered for use on asparagus, carrots, celery, corn (field and sweet), cottonseed

(DuPont has voluntarily canceled use), parsley, parsnips, potatoes, sorghum, soybeans, and wheat (winter). Linuron is also applied to ornamental bulbs, and to poplar trees, for use in shelterbelts, in the mid-west. Linuron may be applied preplant, preemergence, postemergence, or post-transplant using ground or aerial equipment. The registered modes of application are band treatment, directed spray, or broadcast spray. Linuron is a restricted use pesticide and may be applied only by certified applicators or personnel under their direct supervision.

The toxicological data base for linuron is adequate and will support reregistration eligibility.

The product chemistry data is adequate and will support reregistration (clarification of the sources of Drexel's technical products is required). There are sufficient residue chemistry data to support established linuron tolerances for all registered uses on: celery, cottonseed, parsnips, potatoes, and sorghum grain.

Residue data are available to support food additive tolerances for potatoes, granules, at 0.8 ppm and potato chips, at 0.6 ppm; and a required feed additive tolerance on potatoes, waste from processing at, 10 ppm. Delaney issues may prevent the establishment of these tolerances.

HED has used the following toxicology endpoints and dose levels of concern in the risk assessments for linuron:

1) Acute Dietary Endpoint (One Day) Developmental Toxicity in the rabbit - NOEL = 25 mg/kg/day, and LOEL = 100 mg/kg/day;

2) Short Term Occupational or Residential Exposure (1 to 7 Days) Developmental Toxicity in the rat - NOEL = 12.1 mg/kg/day based on maternal and developmental concerns;

3) Intermediate Term Occupational or Residential (1 Week to Several Months) Three-Generation Reproduction Study in the rat - NOEL = 1.25 mg/kg/day based on reduced fertility, and LOEL = 6.25 mg/kg/day; and

4) A dermal absorption rate of 16% (for 8 to 10 hours exposure) was recommended for estimating the systemic dose.

Linuron is classified as a Group C Carcinogen based upon testicular effects in the rat (interstitial cell hyperplasia and adenomas) from a two-year feeding study. Quantification of risk by unit risk is not recommended.

Chronic dietary exposure to the general population is

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expected to be 2% of the Reference Dose. Of the standard subgroups routinely analyzed by the Dietary Risk Evaluation System, the two subgroups with the highest exposures are non-nursing infants less than 1 year old, with expected exposures of 6% of the RfD, and children 1 through 6 years old, with expected exposures 4% of the RfD.

Acute, high-end, exposure to females 13 years of age or older (DRES approximation of women of childbearing age) on any given day is expected to be 1667 times the NOEL for developmental toxicity.

The minimum PPE on each end-use product containing linuron is "coveralls over long sleeved shirt, long pants (except early reentry), chemical-resistant or waterproof gloves (sometimes), and chemical-resistant headgear for overhead exposure."

Margin of exposure (MOE) for certain mixer/loader scenarios are below 100 for both short-term and intermediate-term exposure. Particularly low are those MOE's for mixer/loaders supporting the aerial applications. For those scenarios, MOE's are below 100 for intermediate-term exposure, even with the use of closed mixing/loading systems.

MOE's are also low for handlers using open mixing/loading for ground-boom applications. For this scenario HED recommends closed mixing/loading systems.

Most applications are made early in the season, before reentry tasks are likely, or applications are made to crops that are mechanically harvested. The notable exception is asparagus where applications of linuron are made between asparagus cuttings. Because asparagus harvesting occurs over a long period of time, the use of both the short-term and the intermediate-term end-points are appropriate for addressing postapplication/reentry exposure.

The task specific MOE's for asparagus reentry workers range from:

1) 168 to 931 for short term exposure; and
2) 17 to 96 for intermediate exposure.

HED recommends a restricted-entry interval (REI) of 14 days for all crops. The REI is based solely on the MOE's calculated for asparagus off-loaders handling spears from linuron sprayed fields 14 days after treatment. The data appear to indicate that exposure for asparagus workers is similar, regardless of task, although exposure measurements for harvesters were slightly higher. For crops that have little potential for early reentry exposure, the 14 day REI should not be overly burdensome. For crops such as celery and carrots, where intermediate exposure is likely, the 14 day REI is recommended until worker exposure data are submitted by the registrant and evaluated by the Agency.

The early-entry personal protective equipment requirements established for the products containing linuron are coveralls, chemical-resistant gloves, shoes, and socks.

Due to the short-term and intermediate-term endpoints based on maternal and developmental concerns, OREB establishes minimum applicator personal protective equipment requirements for any end-use product containing linuron. Products containing linuron may contain more stringent PPE, but in no case may they require less stringent PPE than the following: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, and chemical-resistant headgear for overhead exposure.

The following data gaps exist for linuron:

132-1a Foliar Dislodgeable Residues (carrots and celery);
132-1b Soil Dislodgeable Residues (carrots and celery);
133-3 Dermal Exposure (carrots and celery); and
133-4 Inhalation Exposure (carrots and celery).

The Agency requires that foliar and soil dislodgeable residue studies, and dermal and inhalation exposure studies be conducted concurrently.

Residue data to establish tolerances for corn aspirated grain fractions (grain dust) and cottonseed processed fractions are outstanding.

Established linuron tolerances for barley, oats, and rye forage, grain, hay and straw should be revoked since there are no registered uses of linuron on these commodities.

Established tolerances for sweet corn fodder, parsnips tops, and wheat hay should be revoked since these commodities are not listed in Table II as raw agricultural commodities of sweet corn, parsnips, and wheat, respectively.

Field trial data are outstanding for soybeans, forage and hay and sweet corn raw agricultural commodities. Treatment of soybeans is a major linuron use. However, previous dietary exposure estimates conducted in connection with the Linuron Special Review indicate that linuron residues in these commodities will be low and therefore confirmatory. Linuron storage stability data are considered confirmatory.

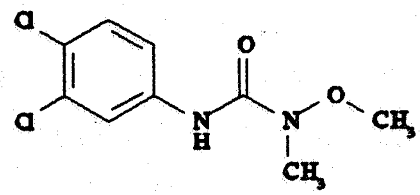
Attachments
cc: D. McNeilly (CBRSII), J. Kariya (SAB), J. Evans (OREB), S. Makris (TOXII)

PRODUCT CHEMISTRY ASSESSMENT

Linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea] is a substituted urea herbicide registered for use on asparagus, carrots, celery, corn (field and sweet), cottonseed (DuPont has voluntarily dropped use), parsley, parsnips, potatoes, sorghum, soybeans, and wheat (winter). Linuron may be applied preplant, preemergence, postemergence, or post-transplant using ground or aerial equipment. The registered modes of application are band treatment, directed spray, or broadcast spray. Linuron is a restricted use pesticide and may be applied only by certified applicators or personnel under their direct supervision.

1. DESCRIPTION OF CHEMICAL

Linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea]:



Empirical Formula: $C_9H_{10}Cl_2N_2O_2$

Molecular Weight: 249.1
CAS Registry No.: 330-55-2
Shaughnessy No.: 035506

2. IDENTIFICATION OF ACTIVE INGREDIENT

Technical linuron is an odorless, white crystalline flake or powder with a melting range of 86-91 C. Linuron is soluble in water at 81 mg/L at 25 C, and is slightly soluble in aliphatic hydrocarbons and moderately soluble in ethanol and common aromatic solvents.

3. MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 9/14/93 identified the linuron manufacturing-use products (MPs) listed in Table 1 registered under Shaughnessy No. 035506. The only current producers of linuron technical are Makteshim-Agan, Israel and Industria Prodotti Chimici, Italy (I.Pi.Ci.).

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Table 1. Registered MPs of linuron.

Formulation	EPA Reg. No.	Registrant	Source(s)	Date Registered
92% T	352-326	E.I. du Pont de Nemours	[redacted]	2/67
95% T	1812-270	Griffin Corporation	[redacted]	2/83
95% T	19713-158		undetermined [a]	10/82
95% T	19713-367	Drexel Chemical Company	undetermined [a]	11/92
95% T	19713-368		undetermined [a]	11/92

[a] Undetermined: HED is unable to determine the source for these products due to conflicting information.

4. REGULATORY BACKGROUND

Assessments as to whether the various sources of technical linuron are substantially similar have been an integral part of the scientific review of the product chemistry database submitted in support of reregistration. The Linuron Guidance Document dated 6/29/84 required that additional data concerning all product chemistry topics be submitted in support of the reregistration of linuron. In addition, the Agency initiated a Special Review in 1984 because linuron was found to exceed the carcinogenicity risk criteria. Special Review ended in 1988 due to the reclassification of linuron as a nonquantifiable Group C carcinogen. The Linuron Reregistration Standard Update, dated 6/20/90, required additional data for the du Pont 92% T and 50% FI, the [redacted] of the Griffin 95% T, and the proposed alternate [redacted] for the Drexel 95% T. Because sources for the registered technical products have changed repeatedly since the Linuron Update, the data requirements have also changed. The current status of the product chemistry data requirements for linuron products is presented in the Appendix. Refer to these tables for a listing of the outstanding product chemistry data requirements.

5. CONCLUSIONS

All pertinent TGAI data requirements are satisfied for the du Pont linuron technical [redacted] Only the nominal concentrations of the product components remain outstanding for the MP requirements for the [redacted] All of the registrants of linuron products must confirm the sources of linuron used for their products. The registrants are required to submit the data required in the summary tables for the linuron technical products, and <u>either</u> certify that the suppliers of the starting materials and the manufacturing process for the linuron TGAIs and MPs have not changed since the last comprehensive product chemistry review <u>or</u> submit a complete updated product chemistry data package.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

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B. HUMAN HEALTH ASSESSMENT

1. TOXICOLOGY ASSESSMENT

The toxicological data base is adequate and will support reregistration of linuron as a food and non-food use pesticide.

A. Acute Toxicity

Acute toxicity values and categories for linuron are summarized in the following table.

TEST	RESULTS	CATEGORY
Oral LD_{50} - rat	2600 mg/kg	III
Dermal LD_{50} - rat	> 2000 mg/kg	III
Inhalation LC_{50} - rat	> 218 mg/L/hr	IV
Eye Irritation - rabbit	Slight conjunctival redness at 24 hrs; clear at 72 hrs	III
Dermal Irritation - rabbit	Not an irritant	IV
Dermal Sensitization - guinea pig	Not a sensitizer	

In an acute oral toxicity study conducted in rats, the oral LD_{50} value for technical (96%) linuron was determined to be 2600 mg/kg (Toxicity Category III) (Consultox Laboratories, Ltd., 1974). In the same study, the dermal LD_{50} in rats was established at >2000 mg/kg (Toxicity Category III). Inhalation exposure of rats to 96% linuron (Kapp, 1975a) resulted in an LC_{50} of >218 mg/L per hour (Toxicity Category IV). These acute oral, dermal, and inhalation studies satisfy guidelines §81-1, §81-2, and §81-3, respectively.

Application of 97.4% linuron to the rabbit eye (Shibata, 1992) resulted in slight conjunctival redness at 24 hours, which was clear by 72 hours (Toxicity Category III). No corneal opacity or irritation of the iris was noted. A primary dermal irritation study in rabbits demonstrated that application of 97.4% linuron produced no irritation (Toxicity Category IV) (Allen, 1993). No dermal sensitization occurred with 95% linuron in guinea pigs (Schulz, 1985). The primary eye and dermal studies and the guinea pig sensitization study satisfy guidelines §81-4, §81-5, and §81-6, respectively.

B. Subchronic Toxicity

A 3-month subchronic study was conducted with linuron in rats at dietary levels of 80, 400, and 3000 ppm (4, 20, and 150 mg/kg/day). Observations of decreased red blood cell count and increased white blood cell count were noted at 400 ppm. At the high-dose (3000 ppm) growth was retarded. Based upon hematological findings, 400 ppm (20 mg/kg/day) was established as the LOEL; the NOEL was 80 ppm (4 mg/kg/day) (US Government, 1963).

The requirement for a 90-day feeding study in dogs (§82-1) was satisfied by the completion of two acceptable chronic studies conducted with linuron in beagles.

C. Chronic Toxicity and Carcinogenicity

In a 1-year dog study (Malley, 1988), 96.2% linuron was fed to groups of 4 beagles/sex/dose at dietary levels of 10, 25, 125, or 625 ppm (male: 0.29, 0.79, 4.17, or 18.6 mg/kg/day; females: 0.3, 0.77, 3.49. or 16.1 mg/kg/day, respectively); this study satisfies the §83-1(b) guideline requirement for a chronic canine toxicity study. In a previous 2-year dog study (E.I. du Pont de Nemours and Co., Inc., 1962), linuron was administered in the diet to beagle dogs at 25, 125, or 625 ppm (0.625, 3.13, or 15.63 mg/kg/day); an abnormal pigment was observed in the blood of animals at all dose levels. Decreased red blood cell count, hematocrit, and hemoglobin levels were also noted in males at 625 ppm. Since the abnormal pigment was postulated to be met- and sulfhemoglobin, assays for these substances were conducted on the 1-year study. The presence of one or both substances in the blood was confirmed for both sexes in the 125 and 625 ppm dose groups at all intervals tested (3, 6, 9, and 12 months). At 625 ppm, evidence of red blood cell destruction was noted as increased hemosiderin deposition on the Kupffer cells of the liver (male and female), slight decreases in erythrocyte count, hemoglobin, and hematocrit levels at all time periods tested, and a small increase in erythropoietic activity in the bone marrow. Secondary hematological changes at 625 ppm included increased platelet count, leukocyte count, and serum cholesterol levels. In addition, absolute liver weight was increased in males at 625 ppm; relative liver weight was increased in males at 125 and 625 ppm. Based upon hematology changes, the LOEL for systemic toxicity was determined as 125 ppm (4.17 mg/kg/day for males; 3.49 mg/kg/day for females). The NOEL for systemic toxicity is 25 ppm (0.79 mg/kg/day for males; 0.77 mg/kg/day for females).

In a 2-year feeding/carcinogenicity study, linuron (97%) was administered to Crl:CD(SD)BR Sprague-Dawley rats at dietary levels of 50, 125, or 625 ppm (2.5, 6.25, or 31.25 mg/kg/day) (Kaplan, 1980). Testicular interstitial cell adenomas were observed at an significantly increased incidence in mid- and

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high-dose males (125 and 625 ppm, respectively). In addition, various indications of blood cell destruction and turnover (increased mean corpuscular volume, decreased red blood cell count, and possible reticulocytosis) were observed in both sexes at 125 and 625 ppm. Analysis of percent hemoglobin to evaluate hematotoxicity (US EPA, 1987) indicated that males were not affected, but percent hemoglobin was decreased for females at 6 and 12 months for the high-dose group, and at 12 months for the mid-dose group. Therefore, based upon hematotoxicity, observed as a decrease in the percent hemoglobin, the LOEL for systemic toxicity for females was 125 ppm (6.25 mg/kg/day). The systemic NOEL for females was 50 ppm (2.5 mg/kg/day), and the systemic NOEL for males was 625 ppm (31.25 mg/kg/day). The requirements for chronic and oncogenicity testing in rodents [guidelines §83-1(a) and §83-2(a)] were satisfied by this study.

In another two-year rat feeding study, in which groups of albino rats were treated with dietary linuron at levels of 25, 125, or 625 ppm (1.25, 6.25, or 31.25 mg/kg/day), the systemic NOEL was determined to be 125 ppm. At the LOEL of 625 ppm (31.25 mg/kg/day), growth retardation was observed. In addition, at that dietary level, hemosiderin content of the spleen was increased for both sexes, marrow fat was reduced for females, the ratio of myeloid-to-erythroid precursors was reduced for males, and the incidence of endometrial hypoplasia was increased for females. These findings were considered to be indicative of hemolysis (Hodge, 1962).

An 18-month feeding study was conducted in Crl:CD(SD)BR rats to study the effects of linuron (94.5%) on methemoglobin and sulfhemoglobin blood concentrations (Pastoor, 1985). The dietary levels tested were 25, 125, or 625 ppm (1.25, 6.25, or 31.25 mg/kg/day). Based upon significant changes noted in blood pigments in mid- and high-dose female rats and in high-dose male rats, the LOEL was determined to be 625 ppm (31.25 mg/kg/day) and 125 (6.25 mg/kg/day) for male and female rats, respectively. The corresponding NOELs for male and female rats were 25 and 125 ppm (1.25 and 6.25 mg/kg/day).

In a two-year feeding/oncogenicity study in CD-1 mice (Wood et al., 1982), linuron was administered in the diet at levels of 50, 150, or 1500 ppm (12, 35, or 455 mg/kg/day). This study satisfied the requirement for a guideline §83-2(b) carcinogenicity study in a second rodent species. A statistically significant increase in the incidence of hepatocellular adenomas was observed at 1500 ppm for female mice, and border-line statistical significance was attained for hepatocellular adenomas at 50 ppm for male mice. At 1500 ppm, body weight and body weight gain were decreased for both males and females throughout the study. Methemoglobin values were increased at all dietary levels for both sexes. Mean absolute and relative liver weights were increased for females at 1500 ppm. For both males and females at that level, histopathological evaluation identified increased incidences of hemosiderosis of the spleen and hepatocytomegaly, hepatocellular cytoplasmic alteration, hepatocellular vacuolization, hemorrhage, and necrosis of the liver. A NOEL was not established; the systemic toxicity LOEL, based on increased methemoglobin values, was $\leq$ 50 ppm (12 mg/kg/day).

Linuron was placed in special Review for carcinogenesis in 1982. It was later classified as a Group C carcinogen with a Q_1* of 2 x 10^{-5} on the basis of a dose-related increase in interstitial cell hyperplasia and adenomas in a two-year rat feeding study (Kaplan, 1980) and hepatocellular tumors that appeared in low-dose male and high-dose female mice in a two-year feeding study (Wood et al., 1982). Subsequent review by the HED peer review committee and the Science Advisory Panel resulted in the elimination of the Q_1*, since the weight of evidence suggested that the carcinogenic potential of linuron in humans is weak, and it should not be regulated as a carcinogen (US EPA, 1989).

D. Developmental Toxicity

In a developmental toxicity study conducted with linuron (97%) in Sprague-Dawley rats, dietary doses of 50, 125, or 625 ppm (5.0, 12.1, or 49.8 mg/kg/day, respectively) were administered on days 6-15 of gestation (Culik, 1979); this study satisfied the guideline §83-3(a) requirement for a developmental toxicity study in rodents. The NOELs for maternal systemic toxicity and developmental toxicity were 125 ppm (12.1 mg/kg/day). The LOEL of 625 ppm (49.8 mg/kg/day) for maternal systemic toxic effects was based upon decreased body weight and food consumption values. The developmental toxicity LOEL of 625 ppm (49.8 mg/kg/day) was based on increases in postimplantation loss and increases in the litter and fetal incidences of resorptions.

When 96.2% linuron was administered by gavage to New Zealand White rabbits at doses of 5, 25, or 100 mg/kg/day on days 7 through 19 of gestation (Hoberman, 1985), a maternal systemic toxicity LOEL was observed at the 25 mg/kg/day level, based upon reduced maternal body weight, thereby defining the NOEL as 5 mg/kg/day. At the high-dose level (100 mg/kg/day), maternal body weight, food consumption, absolute liver weight, and liver-to-body weight ratios were decreased. The developmental toxicity NOEL was determined to be 25 mg/kg/day, based upon an increased number of abortions, decreased mean number of fetuses per litter, decreased fetal body weight, and increased incidence of fetuses with skeletal variations of the skull at the 100 mg/kg/day level (the developmental toxicity LOEL). This study satisfied the guideline §83-3(b) requirement for a developmental toxicity study in rabbits.

E. Reproduction

In a two-generation reproductive toxicity study in Sprague-Dawley rats, dietary levels of 12.5, 100, or 625 ppm linuron (96.2%) (males: 0.84, 6.8, or 44.75 mg/kg/day; females: 1.0, 8.3, or 54.1 mg/kg/day) were administered (Mullin, 1990). This study satisfied the requirement for a guideline §83-4 for a multigeneration reproductive toxicity study in rats. Since no evidence of adverse effects on fertility or reproductive performance was noted, the reproductive toxicity LOEL was undetermined, and the reproductive toxicity NOEL was estimated to be greater than 625 ppm (44.75 and 54.1 mg/kg/day for males and females, respectively). The parental systemic toxicity NOEL was 12.5 ppm, and the systemic LOEL was 100 ppm, based upon decrements in parental body weight gain. In addition, at the 625 ppm level, testicular and epididymal abnormalities (testicular atrophy and intratubular fibrosis; epididymal inflammatory response or oligospermia) and ocular abnormalities (mineralization of the cornea; lens degeneration) were observed at histopathological evaluation of the F1 adults (Stula, 1990). Further evaluation of reproductive organ weight and hormone data from the F1 adults of this 2-generation study combined with an <u>in vitro</u> analysis of the ability of linuron and its metabolites to compete for binding to the androgen receptor resulted in the conclusion that linuron is a weak androgen receptor antagonist (Cook, 1990). These results support the hypothesis that rats exposed to linuron could develop interstitial cell hyperplasia and subsequent adenomas (Leydig cell tumors) of the testicular tissue via a mechanism of sustained hypersecretion of luteinizing hormone induced by the antiandrogenic potential of linuron.

A three-generation reproductive toxicity study in Sprague-Dawley rats (Pastoor, 1984), was conducted with 94.5% linuron at dietary levels of 25, 125, or 625 ppm (approximately 1.25, 6.25, and 31.25 mg/kg/day). Parental systemic effects observed included reduced premating body weight in females of all three generations at 125 and 625 ppm, reduced body weights at weaning for 125 ppm dams, and alopecia in both sexes for the F0 and F1b adults at 625 ppm. Based upon the findings at the mid-dose level, the systemic LOEL was determined to be 125 ppm (6.25 mg/kg/day), and the systemic NOEL was 25 ppm (1.25 mg/kg/day). The reproductive toxicity NOEL was 25 ppm (1.25 mg/kg/day) and the reproductive toxicity LOEL was determined to be 125 ppm (6.25 mg/kg/day), based on the following findings. Fertility was reduced in generations F2a through F3a. Pup survival was consistently decreased for pups at 625 ppm, with most deaths occurring in the first 24 hours postpartum, and a trend for decreased viability from days 1-4. Weanling body weights were decreased for F1b and F2b male and female pups. Absolute liver and kidney weights of weanlings (both sexes) were decreased, and

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histopathology of the F2b weanlings identified a frequent incidence of liver atrophy (decreased cytoplasmic clear spaces of hepatocytes). This study was flawed by the lack of histopathological data on the adult animals; however, the systemic study results are considered to be supportive of those obtained from the two-generation study on linuron (Mullin, 1990).

F. Mutagenicity

Technical linuron did not produce gene mutation in an Ames assay (Russell, 1983), in which Salmonella typhimurium bacteria were tested without activation up to 5.0 µg/plate and with activation up to 100 µg/plate. In an in vitro assay using CHO cells (McCooey, 1983), linuron did not produce gene mutations when tested up to 0.50 mM in a nonactivated system and up to 1.0 mM in an S9-activated system. Similarly, linuron did not induce bone marrow chromosome aberrations in vivo (Farrow et al., 1983), and in other tests for genotoxicity, linuron did not induce unscheduled DNA synthesis in isolated rat hepatocytes (Chromey et al., 1983). These studies met the mutagenicity testing requirements for guidelines §84-2(a), §84-2(b), and §84-4 (gene mutation, structural chromosomal aberration, and other genotoxic effects).

G. Metabolism

The metabolism and tissue distribution of [phenyl-^{14}C](U) linuron was studied in male and female Sprague-Dawley rats. The results of several metabolism studies and communications containing supplemental information were combined to satisfy the requirements for a §85-1 metabolism study. In the first study, labeled linuron was administered as a single gavage dose to 2 rats/sex/dose at 24 mg/kg and 400 mg/kg and also as a single 400 mg/kg gavage dose following dietary pretreatment at 100 ppm (approximately 10 mg/kg) to 2 rats/sex/dose (Carter, 1985a; Carter, 1985b). To further elucidate the metabolic pathway of linuron, a second study was conducted in which a single oral dose of 400 mg/kg of ^{14}C-linuron was administered by gavage to five Sprague-Dawley rats per sex (Hundley, 1991; Brown, 1991; Brown, 1992). The results from these studies indicate that linuron was extensively metabolized by male and female rats at both the low- (24 mg/kg) and high-dose (400 mg/kg) levels when administered by gavage. The majority of the administered ^{14}C-linuron was eliminated in the urine and, to a lesser extent, in the feces, within 96-120 hours. In general, tissue and organ residues were very low (<1%) at both dose levels, and there was no indication of accumulation or retention of linuron or its metabolites. The major metabolites identified in the urine and feces were hydroxy-norlinuron and norlinuron. Approximately 4-5% and 6-8% of the urinary and fecal metabolites, respectively, remained unidentified. Exposure to linuron appears to induce mixed function oxidative enzymes.

H. Reference Dose (RfD) for Chronic Oral Exposure

The RfD for linuron was determined to be 0.0077 (0.008) mg/kg bodyweight per day. This was based on results of a one-year chronic dog study (Malley, 1988) in which hematological changes demonstrated LOELs of 4.17 and 3.49 mg/kg/day for males and females, and NOELs of 0.79 and 0.77 mg/kg/day. The RfD calculation was based upon the NOEL of 0.77 mg/kg/day and used an uncertainty factor of 100 to account for inter-species extrapolation and intra-species variability.

There has been no WHO RfD determination as of yet.

2. EXPOSURE ASSESSMENT

A. Dietary

Tolerances for residues of linuron in/on plant and animal commodities are expressed in terms of linuron *per se* [40 CFR §180.184(a) and (b)]. No food/feed additive tolerances have been established for linuron residues. The established tolerances listed in 40 CFR §180.184 range from 0.25 ppm to 3 ppm. The HED Metabolism Committee has concluded that the residues of concern are linuron and its metabolites convertible to 3,4-dichloroaniline, expressed as linuron (D. McNeilly, 11/17/93); residues of 3,4-dichloroaniline *per se* need not be regulated separately. Adequate enforcement methods are available for the determination of linuron residues of concern in/on plant and animal tissues. The current enforcement methods determine linuron and all metabolites hydrolyzable to 3,4-dichloroaniline.

<u>GLN 171-3: Directions for Use</u>: A REFS search conducted 9/14/93 indicated that there are 15 linuron end-use product (EPs) with food/feed uses which are registered to E.I. du Pont de Nemours and Company, Griffin Corporation, Drexel Chemical Company, Platte Chemical Company, and Micro-Flo Company.

<u>GLN 171-4 (a): Plant Metabolism</u>: The qualitative nature of the residue in plants is adequately understood (D. McNeilly, 11/17/93). Metabolism studies with corn, soybeans, and potatoes indicate that linuron is absorbed from the soil and translocated (i.e., systemic). The metabolic pathway involves demethylation to 3-(3,4-dichlorophenyl)-1-methoxyurea which is further metabolized to 3,4-dichloroaniline; metabolism may also occur through demethoxylation of linuron. The terminal residues of concern are the parent and its metabolites which are convertible to 3,4-dichloroaniline. (MRIDs 00018173, 00018176, 00027624, 00164195, 00164196, 40084801, 41716101, 41716102, 41938101, 42542101, and 42548401).

GLN 171-4 (b): Animal Metabolism: The qualitative nature of the residue in ruminants and poultry is adequately understood (D. McNeilly, 11/17/93). An acceptable metabolism study with goats indicates that linuron is rapidly metabolized by demethylation, demethoxylation, and hydroxylation and is primarily eliminated by excretion. The metabolism of linuron in poultry has been found to be consistent with the goat study. The terminal residues of concern are the parent and its metabolites which are convertible to 3,4-dichloroaniline. (MRIDs 00029932 and 42635401).

GLN 171-4 (c/d): Residue Analytical Methods - Plants/Animals: Adequate enforcement methods are available for the determination of linuron in plant and animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists a colorimetric method (Method I, Bleidner et. al.) and a paper chromatographic method (Method II). Residues of diuron may interfere in Method I. A modified version of Method I (H. L. Pease, *Journal of Agric. and Food Chem.*, 1962, Vol. 10, p. 279), which includes a cellulose column step to separate linuron from diuron, is currently the preferred method for the enforcement of tolerances. Both these methods determine linuron and all metabolites hydrolyzable to 3,4-dichloroaniline and have limits of detection of 0.05 ppm. A GLC/ECD method for linuron residues in/on asparagus from the CA Department of Food and Agriculture has been validated by the Agency and sent to FDA to be published in PAM Vol. II as Method III. This method determines residues of linuron *per se* and the limit of detection is 0.05 ppm. However, this method is inadequate for tolerance enforcement since it does not determine all the residues of concern. In addition, this method uses benzene as the extraction solvent. (MRIDs 00018087, 00018089, 00018127, and 00018176).

The FDA Pestrak Database (PAM Vol. I) contains data concerning the applicability of multiresidue methods D and E (fatty and nonfatty foods) for recovery of linuron and its metabolites 3-(3,4-dichlorophenyl)-1-methoxyurea, 3-(3,4-dichlorophenyl)-1-methylurea, 3,4-dichlorophenyl urea and 3,4-dichloroaniline. Linuron is partially recovered using Multiresidue Method E (fatty and nonfatty foods); recovery using Method D is variable. Linuron metabolites 3-(3,4-dichlorophenyl)-1-methoxyurea, 3-(3,4-dichlorophenyl)-1-methylurea, and 3,4-dichlorophenyl urea are not recovered using Method E (fatty and nonfatty foods); 3-(3,4-dichlorophenyl)-1-methylurea is recovered using Method D but 3-(3,4-dichlorophenyl)-1-methoxyurea is not likely to be recovered using this method. Linuron metabolite 3,4-dichloroaniline is not recovered using Method E (nonfatty foods) and has variable recovery using Method D.

GLN 171-4 (e): Storage Stability: Residues of linuron in/on soybeans, sugar beet tops, wheat, and asparagus have been shown to be stable for up to two years of storage at -20°C.

Storage stability data for the following commodities remain outstanding: carrots (raw and cooked; 19 months); field corn processed commodities (12 months); potatoes, and cooked and processed potato commodities (20 months); and sorghum and sorghum processed commodities (12 months). Additional storage stability data are required to support outstanding field residue and processing studies.

Since residues have been shown to be stable in several matrices, and an interim report on storage stability in the above commodities has been submitted the additional required storage stability data are considered confirmatory.

(MRIDs 43040001, 42913301, 42974401, 43104401, 00159802, 41716103, 42836701, and 42836702).

GLN 171-4 (k): Magnitude of the Residue in Plants: All data for magnitude of the residue in parsley, parsnips, potatoes, and sorghum grain have been evaluated and deemed adequate to reassess tolerances for these commodities.

Field residue data remain outstanding for the following crops: asparagus; carrots; corn, sweet (K + CWHR); corn, sweet, forage; sorghum forage and fodder; soybeans; forage and hay wheat, grain; and wheat forage and straw. (MRIDs 00018067, 00018076, 00018087, 00018089, 00018148, 00018171, 00018172, 00018175, 00018206, 00018375, 00018382, 00018443, 00018450, 00027635, 00163267, 40210901, 40537601, 41189801, 41377601, 41452601, 41452701, 41501501, 41503401, 41569901, 42605901, 43039101, and 43044101).

Sufficient data to reassess tolerances for these commodities are not available at this time. Although sufficient field trial data are not available to reassess tolerances for all crops, sufficient data are available to do a reliable exposure assessment.

Two additional field residue studies on corn (1990; MRID 41510501) and soybean raw agricultural commodities (1990; MRID 41591801) have been submitted. However, data from these submissions were not evaluated because they were generated by Craven Laboratories. Replacement data for field corn commodities and soybean grain were found to be adequate. Replacement data are still needed for sweet corn raw agricultural commodities and soybean forage and hay. The existing feeding restriction prohibiting the feeding of soybean forage and hay should be removed because the feeding restriction is no longer considered practical (see Livestock Feeds Table, 6/94 Subdivision O, Residue Chem. Guidelines).

GLN 171-4 (l): Processed Food/Feed: All data for magnitude of the residue in processed food/feed have been evaluated and deemed adequate except that a full processing study is required for cottonseed and additional data are required to upgrade an existing potato processing study. DuPont in a letter to the Agency (Marie Chubb, 7/23/91) stated that they are canceling linuron use on cotton. If this is the case, the cottonseed processing study will no longer be required.

Outstanding potato processing data are considered confirmatory; sufficient data are available to reassess tolerances and estimate dietary exposure for potato processed products. Food additive tolerances must be proposed for potato chips and granules, and feed additive tolerances must be proposed for wet and dry peel waste.

Because Linuron is assessed as a Group C nonquantifiable carcinogen Delaney issues need to be addressed. (MRIDs 00018206, 40049201, 41241202, 42397201, 42462901, 42542102, and 42560001).

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry and Eggs: All data for magnitude of the residues in meat, milk, poultry, and eggs have been evaluated and deemed adequate. No tolerances are required for poultry and eggs. (MRIDs 00018209, 00018210, 00018375, 00018383, 00018450, 00018775, and 00029932).

Recently the Agency received interim data from DuPont indicating that residue levels of linuron in or on corn fodder exceeded the 1 ppm tolerance. Preliminary data from field trials on corn indicate a tolerance of 6 ppm will be required to cover residues resulting from current registered uses. These data were submitted to the Agency under 6(A) (2) of FIFRA. Since corn fodder is a major feed item for ruminants throughout the U.S. a revision to the previously estimated dietary burden to ruminants is required. The Residue Chemistry Chapter (6/29/82) to the Linuron Registration Standard previously estimated a "maximum plausible dietary load of 1.4 ppm." This estimate utilized the establish tolerance of 1.0 ppm in or on corn fodder. However, assuming residues are present at levels of approximately 6 ppm (the level at which tolerances may be required considering the currently available 6 (a)(2) data) a hypothetical diet based on feeding 50% corn grain and 50% corn fodder would result in a dietary burden of approximately 3.1 ppm.

Based on available ruminant feeding studies HED concludes that established tolerances for meat and milk are adequate to cover the increased dietary burden of 3.1 ppm. It should be noted however that the estimated residue level in ruminant liver (0.81 ppm) and kidney (0.81 ppm) are approaching the established tolerances of 1.0 ppm. Should the currently estimated ruminant dietary burden of 3.1 ppm be increased, established linuron tolerances for ruminant liver and kidney will need to be reassessed.

A final determination concerning the adequacy of meat and milk tolerances cannot be made until all the replacement corn data are submitted.

GLNs 165-1 and 165-2: Confined/Field Rotational Crops: All data for nature of the residue in confined rotational crops have been evaluated and deemed adequate. The requirement for field rotational crop studies has been waived. (MRIDs 40104101 and 40730101). The following are rotational crop restrictions:

"If initial seeding fails to produce a stand, crops registered for the rate of "Lorox" that has been applied may be planted into the treated area."

Unless otherwise directed, any crop may be planted after 4 months except for cereals where only barley, oats, rye, and wheat may be planted.

GLN 171-5: Reduction of Residues: All data for reduction of residues have been evaluated and deemed adequate except that additional information is required to upgrade existing potato and carrot cooking studies. (MRIDs 41241201, 42379901, 42397201, 42462901, and 42462902).

The asparagus cooking study shows washing with water reduces residues by 40%. Boiling removes an additional 25% of the residues, while steaming had little or no effect on reducing residue levels in or on asparagus.

A carrot cooking study was reviewed and found to be unacceptable due to residues below the limit of quantitation. However, the study does indicate that cooking in boiling water does reduce overall residues.

The potato cooking study shows that linuron residues concentrate in or on oven baked potatoes (1.5X) and microwave baked potatoes (1.6X), but are reduced in or on boiled potatoes (0.48X).

B. Residential and Occupational Exposure

Linuron is a substituted urea herbicide used to control germinating and newly emerging grasses and broad-leaved weeds. It is applied to agricultural crops, ornamental bulbs, and to poplar trees, for use in shelterbelts, in the mid-west. Formulations include water dispersable granules, wettable powders, flowable concentrates, and emulsifiable concentrates. Linuron is usually applied after the crop has been planted, but before the weeds emerge. In some cases, over-top sprays are applied to newly emerging crops such as carrots and celery. In asparagus, sprays may be applied between cuttings of newly emerging spears for weed control during harvesting activities.

Current label directions allow for both ground and aerial applications. Although some registered uses are for crops that may be grown in home gardens, EPA is not aware of any products that are labelled primarily for home use.

Postapplication/reentry and mixer/loader/applicator exposure data are required when both toxicity and human exposure criteria are met. The application methods (broadcast and directed) result in direct exposure of mixer/loaders and applicators to the formulated product. When workers enter treated areas to perform hand labor tasks, such as thinning, cultivation, and harvesting, or to perform irrigation-related tasks, they may be exposed to residues on the soil surface and to residues on the foliage following post-emergence applications. Therefore, linuron meets the Agency's human exposure criteria. The HED Toxicology Endpoint Selection Committee identifies two endpoints for assessing short-term and intermediate occupational exposure to linuron. Therefore, linuron meets the toxicity criteria.

<u>Mixer/Loader/Applicator Exposure (Handlers)</u>:

In the Guidance for the Reregistration of Linuron (June 29, 1984), the following personal protective equipment were required for mixer/loader/applicators handling linuron:

One-piece overalls which have long sleeves and long pants constructed of finely woven fabric as specified in the USDA/WPA Guide for Commercial Applicators.

Wide-brimmed hat and heavy-duty fabric work gloves.

Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab which provides a filtered air supply (as described by Taschenberg and Bourke, 1975).

The PPE requirements were based on concerns for linuron as a carcinogen, and that lifetime exposures for mixer/loader/applicators resulted in an unacceptable risk, without those PPE. In a subsequent HED peer review committee and Science Advisory Panel, it was determined that the "carcinogenic potential of linuron in humans is weak, and it should not be regulated as a carcinogen (US EPA, 1989)."

Since the issuance of the Registration Standard in 1984, linuron product labels have been modified in response to PR Notice 93-7, which implemented the labelling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides. These WPS-mandated label modifications established personal protective equipment (PPE) requirements on each end-use product depending on the acute toxicity of the end-use product. However, if the existing labelling contained PPE requirements more stringent than those that the WPS would establish, the more stringent requirements would be retained. Current linuron labels, therefore, may contain a variety of PPE requirements, depending on what other active ingredients and on what inert ingredients are included in a particular formulation, however, the minimum PPE on each end-use product containing linuron is "coveralls over long sleeved shirt, long pants (except early reentry), chemical-resistant or waterproof gloves (sometimes), and chemical-resistant headgear for overhead exposure."

Mixer/loader/applicator (handler) exposure to linuron were derived from data in the Pesticide Handlers Exposure Database (PHED). Exposure for ground-boom and aerial applicators was addressed as well as exposure for mixer/loaders using wettable powder and liquid formulations.

The data in PHED are normalized by pounds of active ingredient handled, and, are referred to as unit exposures. Whenever possible, surrogate unit exposures are chosen from studies having the same PPE as required on the labelling of the chemical currently being evaluated. When data are not available for certain clothing scenarios, existing data points are adjusted using a protection factor based on the type of PPE (eg. a 50% reduction to hand exposure for the use of gloves). Although a 90% protection factor for gloves has been used in the past, a conservative 50% reduction was used in this assessment. The handler assessment presented in this memorandum assumes the use of long sleeved shirt, long pants, gloves, and coveralls. This double layer is an upgrade to existing PPE.

<u>Data Requirements</u>:

132-1a Foliar Dislodgeable Residues (carrots and celery)
132-1b Soil Dislodgeable Residues (carrots and celery)
133-3 Dermal Exposure (carrots and celery)
133-4 Inhalation Exposure (carrots and celery)

The Agency requires that foliar and soil dislodgeable residue studies, and dermal and inhalation exposure studies be conducted concurrently.

3. RISK ASSESSMENT

A. Dietary

The acute dietary endpoint for one day was based on a developmental toxicity study in the rabbit (MRID No. 260064). When 96.2% linuron was administered by gavage to New Zealand White rabbits at doses of 5, 25 or 100 mg/kg/day on days 7 through 19 of gestation, a maternal systemic toxicity was observed at 25 mg/kg/day, based upon reduced maternal body weight. The developmental toxicity NOEL was determined to be 25 mg/kg/day based upon an increased number of abortions, decreased mean number of fetuses per litter, decreased fetal body weight, and increased incidence of fetuses with skeletal variations of the skull at 100 mg/kg/day. The endpoint and dose for use in risk assessment is a NOEL of 25 mg/kg/day (basis described above).

The short term occupational or residential exposure for 1 to 7 days was based on a developmental toxicity study in the rat (MRID No. 0018167). Sprague-Dawley rats were given dietary doses of 50, 125 or 625 ppm (equivalent to 5.0, 12.1 or 49.8 mg/kg/day) on days 6-15 of gestation. The maternal and developmental NOEL is 12.1 mg/kg/day. The LOEL is 49.8 mg/kg/day based upon decreased maternal body weight and food consumption, and increased postimplantation loss and increased in litter and fetal incidences of resorptions (maternal and developmental effects, respectively). The endpoint and dose for use in risk assessment is a NOEL of 12.1 mg/kg/day as described above.

The intermediate term occupational or residential (1 week to several months) was based on a three-generation reproduction study in the rat (MRID No. 00146071). Sprague-Dawley rats were given dietary doses of 0, 25, 125 or 625 ppm linuron (equivalent to 0, 1.25, 6.25 or 31.25 mg/kg/day) through three successive generations. Parental systemic effects observed included reduced premating body weight in females of all three generations at 125 and 625 ppm, reduced body weights at weaning for 125 ppm dams, and alopecia in both sexes for the F0 and F1b adults at 625 ppm. Based upon the findings at the mid-dose level, the systemic LOEL was determined to be 125 ppm (6.25 mg/kg/day), and systemic NOEL was 25 ppm (1.25 mg/kg/day). The reproductive NOEL was also 25 ppm based upon reduced fertility in the F2a through F3a generations at doses of 125 ppm or greater. The endpoint and dose for use in risk assessment is a NOEL of 1.25 mg/kg/day based upon reduced fertility at the LOEL of 6.25 mg/kg/day.

The RfD for linuron was determined to be 0.0077 (0.008) mg/kg bodyweight per day. This was based on results of a one-year chronic dog study (Malley, 1988) in which hematological changes demonstrated LOELs of 4.17 and 3.49 mg/kg/day for males and females, and NOELs of 0.79 and 0.77 mg/kg/day. The RfD

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calculation was based upon the NOEL of 0.77 mg/kg/day and used an uncertainty factor of 100 to account for inter-species extrapolation and intra-species variability.

There has been no WHO RfD determination as of yet.

The Health Effects Division Metabolism Committee discussed the possible significance of 3,4-dichloroaniline residues in plants and animal tissues resulting from treatment with linuron. The Committee expressed concern that 3,4-DCA may be a carcinogen in light of the fact that p-chloroaniline is a quantifiable carcinogen. Because of the low levels found, however, the Committee decided that 3,4-DCA was not of regulatory concern "in connection with the registered use of linuron." (Memo, D. McNeilly to Metabolism Committee Members, 11-17-93.)

Residues

Anticipated Residues from the 1987 Special Review of Linuron were used in the analysis of chronic exposure.

Information on percent of crop treated was supplied by the Biological and Economic Analysis Division (table prepared by G. Ali, December 1993, entitled "Typical Annual Usage (1992) and Percentage of various U.S. Crops Treated with Linuron"). For most crops, the estimate of percent crop treated is the same as or lower than the 1989 estimates provided by BEAD. However, no estimates were supplied for "small grains" in the 1993 table, whereas the estimate was "< 1%" in 1989. In cases where no estimates are supplied, DRES policy is to assume that 100% of the crop is treated. Thus, the percent of crop treated value used in the DRES run went from 1% to 100% for barley, oats, and rye. DRES believes that this is likely to be an overestimate, and that the acute (domestic) use on these crops may even be 0% since there are no registered products for these uses. However, in the absence of confirmation from BEAD, the default value of 100% was assumed.

Although this DRES analysis uses Anticipated Residues and percent of crop treated where available, a separate part of the analysis uses tolerances to estimate theoretical maximum exposure. The tolerance reassessment suggested that some tolerances should be revoked (barley, oats, rye, and popcorn) or that there were insufficient data to support a tolerance (asparagus, sheep). In these cases, the DRES analysis used the existing tolerance rather than the reassessed tolerance. The resulting Theoretical Maximum Residue Contribution is thus likely to be higher than what would be expected if all of the tolerances suggested in the tolerance reassessment were implemented. (It is possible, however, that a reassessed tolerance for asparagus and sheep could raise exposure above what is estimated in the TMRC.)

For the acute dietary exposure analysis, tolerance values were used. Anticipated residues for acute analysis were not provided. Information on percent of crop treated was not used.

Proposed tolerances for lettuce, ginger, and taro, and proposed tolerance revisions for potatoes and meat byproducts, are not included in this DRES analysis.

No residue levels for impurities were provided to DRES.

Results

Chronic exposure: Exposure to the general population is expected to be approximately 0.000185 mg/kg bodyweight/day, or 2% of the Reference Dose. Of the standard subgroups routinely analyzed by the Dietary Risk Evaluation System, the two subgroups with the highest exposures are non-nursing infants less than 1 year old, with expected exposures of 0.000485 mg/kg/day (6% of the RfD), and children 1 through 6 years old, with expected exposures of 0.000343 mg/kg/day (4% of the RfD).

Acute exposure: High-end exposure to females 13 years of age or older (DRES' approximation of women of childbearing age) on any given day is expected to be 0.015 mg/kg/day, or 1667 times the NOEL for developmental toxicity. Mean exposure is expected to be 0.003365 mg/kg/day, or more than 7400 times the NOEL for developmental toxicity. Nearly 100% of women in this age group eat at least one commodity which has a tolerance level for linuron.

The estimate of acute exposure is likely to be an overestimate inasmuch as it assumes that consumers will eat tolerance levels of linuron residue on all items simultaneously. This is an unlikely occurrence, given that less than 100% of an given crop is treated with linuron, and that residues are rarely at tolerance level on all fields that are treated.

C. Occupational and Residential

Occupational and Residential risk

Table 3 gives the MOE's for applicator and mixer/loader exposure scenarios. Information regarding the studies from which the surrogate data were selected, is provided in Table 4. For all of the applicator scenarios, margins of exposure (MOE) are greater than 100. However, MOE's for certain mixer/loader scenarios are below 100 for both short-term and intermediate-term exposure. Particularly low, are those MOE's for mixer/loaders supporting the aerial applications. For those scenarios, MOE's are below 100 for intermediate-term exposure, even with the use of closed mixing/loading systems.

MOE's are also low for handlers using open mixing/loading for ground-boom applications. MOE's for closed mixing/loading systems appear to be adequate.

Margins of exposure may be calculated from:

$$MOE = \frac{NOEL}{exposure}$$

- ~~The NOEL = 12.1 mg/kg/day for short-term (1-7 days) exposure~~

- The NOEL equals 1.25 mg/kg/day for intermediate (> 7 days) exposure

<u>Postapplication/Reentry Exposure (Workers)</u>:

The potential for postapplication/reentry exposure is unlikely following most applications of linuron. This is because most applications are made early in the season before reentry tasks are likely or are made to crops that are mechanically harvested. The notable exception is asparagus where applications of linuron are made between asparagus cuttings. Current labelling indicates a 24-hour reentry interval, which was established in the 1984 Guidance Document. The 24-hour reentry interval established by the 1984 Guidance Document was converted into a 24-hour restricted-entry interval through modifications to the labelling specified in PR Notice 93-7, which implemented the labelling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides.

To formally establish a REI, the registrant submitted a worker exposure study addressing asparagus worker exposure "Exposure of Asparagus Harvesters to Lorox® (Linuron) Herbicide in California, 1986" (MRID 403418-01). In the study, the registrant measured exposures for three worker tasks; harvesters, sledders, and off-loaders. Harvesters cut the spears and leave them in bundles at various locations in the field. Sledders drive a tractor and wagon along the field and pick up the bundles of asparagus left by the harvesters. Off-loaders unload the asparagus from the wagons at the packing house. Because asparagus harvesting occurs over a long period of time, the use of both the short-term and the intermediate-term end-points are appropriate for addressing postapplication/reentry exposure.

The study "Exposure of Asparagus Harvesters to Lorox® (Linuron) Herbicide in California, 1986" [MRID 403418-01] is considered supplemental, and can be used to evaluate the current use of linuron on asparagus. The sampling schedule was limited to 0 day, 1 day, and 3 days postapplication because of inclement weather. Therefore, a dissipation curve could not be established. However, off-loader exposure was measured on the first day of the study for workers handling asparagus treated 14 days prior to the initiation of the study. High winds and other complicating factors rendered the inhalation data unacceptable. OREB decided to use these supplemental data because the major route of exposure is via the dermal route. The task specific worker MOE's are presented in the following table:

MOE's for Asparagus Reentry Workers

TASK (DAT)	HOURLY EXPOSURE (mg/hour)	AVERAGE DAILY EXPOSURE (ADE) (mg/kg/day)	Short-Term (1 - 7 da) MOE	Intermediate (> 7 da) MOE
Harvest (1)	3.386	0.072	168	17
Sledder (1)	2.161	0.046	263	27
Off-Loader (1)	2.022	0.043	281	29
Harvest (3)	1.562	0.033	367	38
Sledder (3)	0.619	0.013	931	96
Off-Loader (3)	1.446	0.031	390	40
Off-Loader* (14)	0.6	0.013	931	96

DAT - Days After Treatment

* Exposed to asparagus treated at a rate of 1 lb ai/acre, 14 days before this exposure measurement.

$$ADE = \frac{\text{hourly exposure} \times 8\ \text{hr}}{60\ \text{kg (body wt.)}} \times 16\%\ \text{(dermal absorption rate)}$$

Restricted-Entry Interval (REI):

HED recommends a restricted-entry interval (REI) of 14 days for all crops. The REI is based solely on the MOE's calculated for asparagus off-loaders handling spears from linuron sprayed fields 14 days after treatment. The data appear to indicate that exposure for asparagus workers is similar, regardless of task, although exposure measurements for harvesters were slightly higher. For crops that have little potential for early reentry exposure, the 14 day REI should not be overly burdensome. For crops such as celery and carrots, where intermediate exposure is likely, the 14 day REI is recommended until worker exposure data are submitted by the registrant and evaluated by the Agency.

The early-entry personal protective equipment requirements established for the products containing linuron are coveralls, chemical-resistant gloves, shoes, and socks.

Personal Protective Equipment (PPE) Requirements:

The personal protective equipment requirements for products containing linuron should, in general, be established based on the acute toxicity of the end-use product by route of entry as described in PR Notice 93-7 or other EPA guidance. However, due to concerns for the short-term and intermediate-term risks HED establishes minimum applicator personal protective equipment requirements for any end-use product containing linuron. Products containing linuron may contain more stringent PPE, but in no case may they require less stringent PPE than the following: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, and chemical-resistant headgear for overhead exposure.

Closed-system mixing/loading is recommended for the ground-boom applications based on the low intermediated exposure MOE's for mixer/loader exposure. PPE similar to that required for the applicator must be available to the mixer/loader, in the event of a spill or leak.

Since the Agency is unaware of any linuron end-use products that are primarily intended for home-use, HED will not establish entry restrictions or personal protective equipment requirements for those products at this time.

Table 3. Summary Exposure Values for Linuron[A]

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre)[B]	Daily Maximum Treated (acres)[C]	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE[D] Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE	Intermediate exposure MOE
									1 to 7 days	7 days to several months
Mixer Loader Exposure Levels										
Open Pour Liquids (I)	Aerial	Variable	Variable	1 - 2.5	350	0.113	0.00057	0.11 - 0.27	45 - 110	5 - 11
Open Mix Wettable Powder (II)	Aerial	Variable	Variable	1 - 2.5	350	0.2	0.0037	0.21 - 0.52	23 - 58	2 - 6
Open Pour Liquids (I)	Ground-boom	Variable	Variable	1 - 2.5	100	0.113	0.00057	0.03 - 0.08	151 - 403	16 - 42
Open Mix Wettable Powder (II)	Ground-boom	Variable	Variable	1 - 2.5	100	0.2	0.0037	0.06 - 0.15	81 - 202	8 - 21
Closed Mix (III)	Ground-boom	Variable	Variable	1 - 2.5	100	0.02	0.0003	0.006 - 0.015	> 500	83 - 208
Closed Mix (III)	Aerial	Variable	Variable	1 - 2.5	350	0.02	0.0003	0.02 - 0.05	> 200	25 - 63
Applicator Exposure Levels										
Ground-boom Application (IV)	Broadcast	Asparagus, Direct Seeded or newly planted crowns	Preemergence	1 - 2 Two lb ai per season	50	0.014	0.0004	0.002 - 0.004	> 1000	> 300
Ground-boom	Broadcast	Asparagus, Direct Seeded or newly planted crowns	Postemergence	0.5 - 1 One to two applications per season	50	0.014	0.0004	0.001 - 0.002	> 1000	> 500
Ground-boom	Broadcast	Asparagus, Established Beds	Preemergence	1 - 2 One application	50	0.014	0.0004	0.002 - 0.004	> 1000	> 300
Ground-boom	Broadcast	Asparagus, Established Beds	Postemergence, before cutting season or immediately after cutting	0.5 - 1 One to four applications	50	0.014	0.0004	0.001 - 0.002	> 1000	> 500

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Table 3 (continued)

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre)[B]	Daily Maximum Treated (acres)[C]	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE[D] Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE	Intermediate exposure MOE
									1 to 7 days	7 days to several months
Ground-boom	Broadcast	Asparagus, Established Beds (fern stage)	Directed Postemergence	2 - 4 One application	50	0.014	0.0004	0.004 - 0.004	> 1000	> 100
Ground-boom	Broadcast	Bulbs, (calla lily, daffodil, tulip, Dutch iris)	After Planting, before plants emerge	1 One application	25	0.014	0.0004	0.001	> 1000	> 1000
Ground-boom	Broadcast	Carrots, Florida	Preemergence	0.5 - 1 No more than 2 lb ai per season	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Ground-boom	Broadcast	Carrots, Ohio Michigan, and Wisconsin	Preemergence	0.5 - 1.5 No more than 2 lb ai per season	60	0.014	0.0004	0.001 - 0.004	> 1000	> 250
Ground-boom	Broadcast	Carrots, East of the Rocky Mountains	Postemergence, Non-directed spray after carrots are 3" tall	0.75 - 1.5 A repeat application may be made. No more than 2 lb ai/crop	15	0.014	0.0004	0.001	> 1000	> 1000
Ground-boom	Broadcast	Celery, East of the Rocky Mountains	Non-Directed Spray After Transplanting	0.75 - 1.5 One application	100	0.014	0.0004	0.003 - 0.007	> 1000	> 150
Ground-boom	Broadcast	Corn, East of the Rocky Mountains	Preemergence, after planting	0.375 - 1.5 One application	100	0.014	0.0004	0.002 - 0.007	> 1000	> 150
Ground-boom	Broadcast	Corn (Field and Sweet)	Postemergence, directed spray after corn is at least 15" high	0.625 - 1.5 One application	100	0.014	0.0004	0.003 - 0.007	> 1000	> 150
Ground-boom	Broadcast	Parsley, Texas	Preemergence, after planting	1.5 One application	25	0.014	0.0004	0.002	> 1000	> 700

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Table 3 (continued)

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre)[B]	Daily Maximum Treated (acres)[C]	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE[D] Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE	Intermediate exposure MOE
									1 to 7 days	7 days to several months
Ground-boom	Broadcast	Parsnips	Preemergence, after planting	0.75 - 1.5 One application	15	0.014	0.0004	0.001	> 1000	> 1000
Ground-boom	Broadcast	Poplar (Shelterbelt), Midwest	Directed spray after bud break in the spring	1 - 2 No more than 4 lb ai/year	25	0.014	0.0004	0.001 - 0.002	> 1000	> 600
Ground-boom	Broadcast	Potatoes, East of the Rocky Mountains	Preemergence, after planting	0.75 - 2 One application	100	0.014	0.0004	0.003 - 0.007	> 1000	> 150
Ground-boom	Broadcast	Potatoes, Wisconsin (Central Sands Area)	Preemergence, after planting	0.5 - 1 One application	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Ground-boom	Broadcast	Sorghum	Preemergence	0.313 - 1 One application	100	0.014	0.0004	0.001 - 0.004	> 1000	> 300
Ground-boom	Broadcast	Sorghum	Postemergence, Directed spray	0.5 - 1 One application	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Ground-boom	Broadcast	Soybeans, Conventional Tillage	Preemergence	0.16 - 2.5 One application	100	0.014	0.0004	0.001 - 0.01	> 1000	> 100
Ground-boom	Broadcast	Soybeans, Minimum or No-Tillage	Preemergence	0.375 - 2.5 One application	100	0.014	0.0004	0.001 - 0.01	> 1000	> 100
Ground-boom	Broadcast	Soybeans	Postemergence, Directed spray	0.5 -1 Up to two applications not to exceed 1 lb ai	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Aerial (total deposition) (V)	Broadcast	Variable	Variable (not including directed sprays)	1 - 2.5	350	0.004	0.0002	0.005 - 0.01	> 1000	> 100

[A] Liquid and wettable powder linuron formulations were chosen to represent best and worst case scenarios respectively.

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B A range of application rates are provided whenever the amount used is based on soil types, cropping systems, tank mixes, or weed species.

C Daily maximum treated acres are based either on the amount acreage that can be treated in one day or based on average farm size. The average farm size is based on data presented in the 1987 Census of Agriculture. These values should be validated/refined by BEAD if the exposure assessment needs to be refined.

D The Average Daily Exposure (ADE) (mg/kg/day) = [(Exposure (mg/lb ai) * Appl. Rate (lb ai/acre) * Acres Treated)/60 kg]. A 16% dermal absorption rate was assumed for dermal exposure and 100% absorption was assumed for inhalation exposure. Values presented in this column were rounded to the second decimal place for mixer/loaders and to the third decimal place for applicators. The Margins of Exposure (MOE) were calculated using the unrounded values.

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Table 4. Exposure Scenario Descriptions for Linuron[a]

Exposure Scenario (Scene #)	Data Source	Clothing Scenario	Equipment	Formulations	Standard Assumptions (8-hour work day)	Comments
Mixer/Loader Exposure Levels						
Open Pour Liquids (I)	PHED	Long Pants, Long-Sleeves, No Gloves	Open System	All Liquids	For all liquid formulations plus dry flowables such as water dispersable granulars	Acceptable PHED grades, 14+ replicates, 50% protection factor applied to hand exposure to account for the use of chemical resistant gloves.
Open Mix Wettable Powders (II)	PHED	Total Deposition	Open System	PHED Wettable Powder Category	Wettable powder only	All PHED grades, 3 to 14 replicates, 50% protection factor applied to dermal and to hand exposure levels to account for the use of normal work clothing and chemical resistant gloves.
Closed Mix Liquids (III)	PHED	Total Deposition	Closed System	PHED Closed System Category	All closed systems considered similar for this assessment	PHED grades A/B/C, 13 replicates, 50% protection factor applied to dermal and to hand exposure levels to account for the use of normal work clothing and chemical resistant gloves.
Applicator Exposure Levels						
Ground-boom Application (IV)	PHED	Long Pants, Long-Sleeves, No Gloves	PHED Ground-boom Category/Open Cab	All Formulations	Tractor based ground-boom	PHED grades A/B/C, 6+ replicates, 50% protection factor applied to hand exposure to account for the use of chemical resistant gloves, and for the use of coveralls.
Aerial (V)	PHED	Long Pants, Long-Sleeves, No Gloves	PHED Aerial Fixed Wing Category	All Formulations	All fixed-wing aerial data	No helicopter data available, all PHED grades, 4 to 41 replicates, 50% protection factor applied to hand exposure to account for the use of chemical resistant gloves when entering and exiting aircraft.

• All exposure levels presented in Appendix 1 reflect the current PPE requirements for linuron handlers. Any exposure values which did not reflect the required clothing scenario were adjusted using protection factors (see comments). Unit dermal exposure was assumed to be 50 percent hand exposure and 50 percent remaining dermal exposure. All dermal exposure values are the "best" fit mean. The "best" fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types.

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Data Gaps and Additional Requirements

Residue Chemistry

Residue data are outstanding and must be provided to establish required tolerances for corn aspirated grain fractions (grain dust) and cottonseed processed fractions.

Field trial data are outstanding for soybeans, forage and hay and sweet corn raw agricultural commodities. Treatment of soybeans is a major linuron use. However, previous dietary exposure estimates conducted in connection with the Linuron Special Review indicate that linuron residues in these commodities will be low and therefore confirmatory. Linuron storage stability data are considered confirmatory.

OREB

132-1a Foliar Dislodgeable Residues (carrots and celery)
132-1b Soil Dislodgeable Residues (carrots and celery)
133-3 Dermal Exposure (carrots and celery)
133-4 Inhalation Exposure (carrots and celery)

The Agency requires that foliar and soil dislodgeable residue studies, and dermal and inhalation exposure studies be conducted concurrently.

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REFERENCES

Toxicology

Allen, D.J. (1993) Linuron Technical: Primary Skin Irritation Test in the Rabbit: Project No. 498/21. Unpublished study prepared by Safepharm Laboratories Ltd., Derby, U.K. MRID No. 428490-02.

Brown, A. (1991) Supplement No. 1 to Metabolism of [Phenyl-[Carbon-14](U)] Linuron by the Laboratory Rat: Haskell Laboratory Report No. 351-91; Medical Research No. 1448-89. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 42006801.

Brown, A. (1992) Supplement No. 2 to Metabolism of [Phenyl-[Carbon-14](U)] Linuron by the Laboratory Rat: Haskell Laboratory Report No. 351-91; Medical Research No. 1448-89. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 42318701.

Carter, L. (1985a) Metabolism of [Phenyl-[Carbon-14](U)] Linuron by Male and Female Rats: Document No. AMR-250-84. Unpublished study prepared by E.I. du Pont de Nemours and Company. MRID No. 00146489.

Carter, L. (1985b) Supplement to: Metabolism of [Phenyl-[Carbon-14](U)] Linuron by Male and Female Rats: Document No. AMR-250-84. Unpublished study prepared by E.I. du Pont de Nemours and Company. MRID No. 40142401.

Chromey, N., Horst, A., McCooey, K. (1983) Unscheduled DNA Synthesis/Rat Hepatocytes <u>In Vitro</u>: Haskell Laboratory Report No. 190-83; Medical Research No. 4581-067. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 00132583.

Consultox Laboratories, Limited (1974) Linuron: Acute Oral and Dermal Toxicity Evaluation: CL74:46:996G. Unpublished study submitted by Industrial Prodotti Chimici, s.p.a. MRID No. 00027625.

Cook, J.C. (1990) Investigation of a Mechanism for Leydig Cell Tumorigenesis by Linuron in Rats: Haskell Laboratory Report No. 494-90. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 41630101.

Culik, R. (1979) Teratology Study of 3-(3,4-Dichlorophenyl)-1-Methoxy-1-Methylurea in Rats: Haskell Laboratory Report No. 33-79. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 00018167.

33

E.I. du Pont de Nemour and Co., Inc. (1962) In: US Government, 1963, Memorandum from M.L. Quaite to F.J. McFarland, dated 4/29/63. Evaluation of Pharmacological Data Submitted in Petition to Establish Residue Tolerances...for 3-(3,4-Dichlorophenyl)-1-Methoxy-1-Methylurea, Commonly Known as Linuron, (information regarding 2-year chronic study in dogs), Document No. 000681. Unpublished study submitted by E.I. du Pont de Nemours and Company. MRID Nos. 00018374 and 00018376.

Farrow, M., Cortina, T., Padilla-Nash, H. (1983) In Vivo Bone Marrow Chromosome Study in Rats: Linuron: HLA Project No. 201-584. Final Report. Unpublished study conducted by Hazleton Laboratories America, Inc. MRID No. 00137153.

Hoberman, A. (1985) Developmental Toxicity Study of INZ-326 Administered Via Gavage to New Zealand White Rabbits: Final Report: Protocol 104-009. Unpublished study prepared by Argus Laboratories, Inc. MRID No. 00153867.

Hodge, H.C. (1962) In: US Government, 1963, Memorandum from M.L. Quaite to F.J. McFarland, dated 4/29/63. Evaluation of Pharmacological Data Submitted in Petition to Establish Residue Tolerances...for 3-(3,4-Dichlorophenyl)-1-Methoxy-1-Methylurea, Commonly Known as Linuron, (information regarding 2-year carcinogenicity study in rats), Document No. 000681. Unpublished study conducted by The University of Rochester and submitted by E.I. du Pont de Nemours and Company. MRID No. 00018379.

Hundley, S. (1991) Metabolism of [Phenyl-[Carbon-14](U)] Linuron by the Laboratory Rat: Haskell Laboratory Report No. 351-91; Medical Research No. 1448-89. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 41960001.

Kaplan, A.M., McAlack, J.W., Hall, C.L., et al. (1980) Long-Term Feeding Study in Rats with 3-(3,4-Dichlorophenyl)-1-Methoxy-1-Methylurea (Lorox®; Linuron; INZ-326): Haskell Laboratory Report No. 100-80. Unpublished study submitted by E.I. du Pont de Nemours and Company. MRID No. 00029680.

Kapp, R.W. (1975) Final Report: Acute Inhalation Toxicity Study in Rats: Project No. M915-103. Unpublished study prepared by Hazleton Laboratories America, Inc. MRID No. 00053769.

Malley, L. (1988) Chronic Toxicity Study with IN Z326-118: One-Year Feeding Study in Dogs: Report No. 181-88; Medical Research Project No. 8031-001. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 40952601.

McCooey, K. (1983) CHO/HGPRT Assay for Gene Mutation: Linuron: Haskell Laboratory Report No. 540-83; Medical Research No. 4581-067. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 00137152.

Mullin, L. (1990) Reproductive and Fertility Effects with IN

34

Z326-118 (Linuron), Multigeneration Reproduction Study in Rats: Medical Research Project No. 8511-001: Haskell Laboratory Report No. 20-90. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 41463401.

Pastoor, T.P. (1984) Multigeneration Reproduction Study in Rats with 3-(3,4-Dichlorophenyl)-1-Methoxy-1-Methylurea (Lorox®, Linuron, INZ-326): Haskell Laboratory Report No. 436-84. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 00146071.

Pastoor, T.P. (1985) Effect of INZ-326 on Methemoglobin and Sulfhemoglobin Concentrations in the Rat: Haskell Laboratory Report No. 521-85; Medical Research Project No. 7606-001. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 00149883.

Russell, J. (1983) Mutagenicity Evaluation in Salmonella typhimurium: Haskell Laboratory Report No. 106-83; Medical Research No. 4581-067. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 00131738.

Schulz, M. (1985) Guinea Pig Maximization Test Using Linuron Technical: Intox Sample No. 584: Project No. GRF-AT-008. Unpublished study prepared by Intox Laboratories. MRID No. 00146868.

Shibata, R. (1992) Primary Eye Irritation Study of Linuron Technical in the Rabbits: Project No. BOZO/B-2177. Unpublished study prepared by Bozo Research Center, Inc., Tokyo, Japan. MRID no. 428490-01.

Stula, E. (1990) Reproductive and Fertility Effects with IN Z326-118 (Linuron) Multigeneration Reproduction Study in Rats: Revised Supplemental: Medical Research Project No. 8511-001: Haskell Laboratory Report No. 20-90. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 41864701.

US Government (1963) Memorandum from M.L. Quaite to F.J. McFarland, dated 4/29/63. Evaluation of Pharmacological Data Submitted in Petition to Establish Residue Tolerances...for 3-(3,4-Dichlorophenyl)-1-Methoxy-1-Methylurea, Commonly Known as Linuron, (information regarding 3-month subchronic study in rats, conducted at Haskell Laboratories). Document No. 000681.

US EPA (1987) Linuron Rat Study - Evaluation of Hematological Measure - Hb (g%). Memo from Bernice Fisher to James Rowe, dated 5/21/87. Document No. 005926.

US EPA (1989) Linuron: Conclusion of the Special Review. [OPP-30000/41C](FRL-3510-3) Federal Register 54(17):4072.

35

Wood, C., Rickard, R., Hall, C., et al. (1982) Long-term Feeding Study with Lorox®, Linuron, INZ-326 in Mice: Final Report, Haskell Laboratory Report No. 758-82. Unpublished study prepared by E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine. MRID No. 00124195.

Chemistry References (used to support established tolerances)

00018067 E.I. du Pont de Nemours & Company (1961) Residue Data - Linuron - Sweetcorn. (Unpublished study received Apr 8, 1963 under unknown admin. no.; CDL:124702-B)

00018076 E.I. du Pont de Nemours & Company (1967) Residue Information. (Unpublished study received Jan 10, 1968 under 352-270; CDL:124701-A)

00018087 California. Department of Food and Agriculture (19??) Determination of Linuron Residues on Asparagus. Undated method. (Unpublished study/received Mar 20, 1973 under 3E1373; CDL:093663-B)

00018089 California. Department of Agriculture (1974) Linuron Recoveries from Asparagus by Alkaline Hydrolysis (200 gram samples). Method dated Jul 31, 1974. (Unpublished study received on unknown date under 3E1373; CDL:093662-B)

00018127 E.I. du Pont de Nemours and Company (1962) Determination of 3-(3,4-Dichlorophenyl)-1-methoxy-1-methylurea (Linuron) in Soils and Plant Tissue. (Unpublished study received Nov 8, 1962 under 352-270; CDL:026676-D)

00018148 E.I. du Pont de Nemours & Company (1970) Residue Data: Table A. (Unpublished study received Sep 16, 1971 under 352-270; CDL:125817-A)

00018171 E.I. du Pont de Nemours & Company, Incorporated (1966) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil. (Unpublished study received Oct 5, 1966 under 7F0542; CDL:090665-C)

00018172 E.I. du Pont de Nemours & Company, Incorporated (1963) Residue Data: Linuron - Carrots: Pre-emergence Treatment. (Unpublished study received Oct 5, 1966 under 7F0542; CDL:090665-D)

00018173 Belasco, I.J. (1967) Absence of Tetrachloroazobenzene in Soils Treated with Diuron and Linuron. (Unpublished study received on unknown date under 7F0542; submitted by E.I. du Pont de Ne-mours & Co., Inc., Wilmington, Del.; CDL:092830-A)

00018175 E.I. du Pont de Nemours and Company (19??) Residue Data: Linuron - Diuron: Cereal Grains. (Unpublished study received Oct 14, 1966 under 7F0542; CDL:092830-D)

00018176 Reasons, K.M.; Furtick, W.R.; Atkeson, G.A.; et al. (1966) Additional Data in Support of Petition. (Unpublished study received Oct 14, 1966 under 7F0542; submitted by E.I. du 36

Pont de Nemours& Co., Inc., Wilmington, Del.; CDL:092830-G)

00018206 E.I. du Pont de Nemours and Company (1962) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil: [Linuron]. (Unpublished study received Apr 13, 1963 under PP0356; CDL:092640-E)

00018209 E.I. du Pont de Nemours & Company, Incorporated (1954?) Feeding Study at 1 PPM in Corn Fodder. (Unpublished study received Apr 13, 1963 under PP0356; CDL:092640-I)

00018210 E.I. du Pont de Nemours & Company, Incorporated (1954?) Feeding Study at 50 PPM in Total Daily Diet. (Unpublished study received Apr 13, 1963 under PP0356; CDL:092640-J)

00018375 E.I. du Pont de Nemours and Company (1962) Linuron Livestock Feeding Studies: Milk and Meat. (Unpublished study received Feb 7, 1963 under PP0356; CDL:090386-B)

00018382 E.I. du Pont de Nemours & Company (1962) Residue Data: Linuron - Sweetcorn - 1962. (Unpublished study received Apr 13, 1962 under 352-270; CDL:090385-D)

00018383 E.I. du Pont de Nemours and Company (1963) Linuron: Poultry Feeding Studies: Residue Data - Tissues and Eggs. (Unpublished study received Apr 13, 1962 under 352-270; CDL:090385-E)

00018443 E.I. du Pont de Nemours & Company, Incorporated (1970) The Results of Tests on the Amount of Linuron Residue Remaining on or in Celery including a Description of the Analytical Method Used. (Unpublished study received Apr 18, 1971 under 1E1148; submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:090935-A)

00018450 E.I. du Pont de Nemours and Company, Incorporated (1961) Du Pont Herbicide 326 - Corn. (Unpublished study received on unknown date under PP0356; CDL:098656-A)

00018775 E.I. du Pont de Nemours and Company, Incorporated (1961) Linuron - Livestock Feeding Studies. (Unpublished study received on unknown date under PP0356; CDL:098656-B)

00027635 E.I. du Pont de Nemours & Company, Incorporated (1963) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil: [Linuron]. (Unpublished study received Feb 18, 1963 under PP0413; CDL:090447-B)

00027624 E.I. du Pont de Nemours and Company (1966) Name, Chemical Identity, and Composition: [Linuron]. (Unpublished study received Oct 14,1966 under 7F0542; CDL:092830-E)

00029932 Belasco, I.J. (1979) The Metabolism of 14C-Phenyl Labeled Linuron in the Lactating Nanny Goat. (Unpublished study received Jan 21, 1980 under 352-270; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:241635-C)

37

00159802 E.I. du Pont de Nemours & Co., Inc. (1978) Linuron Freezer Storage Study on Soybean and Sugarbeet Tops. Unpublished study. 14 p.

00163267 E. I. du Pont de Nemours & Co., Inc. (1986) Linuron Residue Study: Response to Special Review/Reregistration Guidance Document - EPA Case No. 47 (6/29/84). Unpublished compilation. 159 p.

00164195 Fuesler, T. (1986) Metabolism of Carbon 14 -Linuron in Field-grown Soybean Plants: Document No. AMR-570-86. Unpublished study prepared by E. I. du Pont de Nemours & Co., Inc. 49 p.

00164196 Ferguson, E. (1986) Metabolism of Carbon 14 -Linuron by Potato Plants: Document No. AMR-559-86. Unpublished study prepared by E. I. du Pont de Nemours & Co., Inc. 35 p.

40049201 McIntosh, C. (1986) Linuron Processing Studies - Potatoes: Du Pont Study No. AMR-587-86 No. 1. Unpublished study prepared in cooperation with National Food Laboratory and Enviro-Bio-Tech., Ltd. 33 p.

40084801 Ferguson, E. (1986) Metabolism of Carbon 14 -Linuron by Corn Plants: Laboratory Project ID. AMR-642-86. Unpublished study prepared by E. I. du Pont de Nemours and Co., Inc. 64 p.

40104101 Erbes, D. (1986) Confined Accumulation Study of Phenyl(U)-carbon 14 Linuron on Rotational Crops: Laboratory Project ID:AMR-609-86. Unpublished study prepared by E. I. du Pont de Nemours & Co., Inc. 53 p.

40210901 E.I. du Pont de Nemours & Co. (1987) Linuron Residue Study: Supplement: Response to Special Review/Reregistration Guidance Document: Lab Project ID: 47. Unpublished compilation prepared in cooperation with Enviro-Bio-Tech, Ltd. 676 p.

40537601 E. I. du Pont de Nemours & Co., Inc. (1988) Linuron Residue Study: Response to Special Review/Reregistration: Du Pont EPA Case No. 47. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 268 p.

40730101 Erbes, D. (1988) Supplement to: Confined Accumulation Study of [Phenyl(U)-[Carbon 14]] Linuron on Rotational Crops ...: Laboratory Project ID: AMR 609-86. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 85 p.

41189801 Baron, J. (1989) Linuron: Magnitude of Residue on Parsley: Project ID: IR-4 PR No. 925/3035/3629. Unpublished study prepared by Cornell University, IR-4 Northeast Region. 74 p.

41241201 Fujinari, E.; Guinivan, R. (1989) Reduction of Linuron Residues During Cooking of Carrots, Asparagus, and Potatoes: Laboratory Project ID AMR-587-86. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. in cooperation with Enviro-Bio-Tech., Ltd. 83 p.

38

41241202 Guinivan, R. (1989) Magnitude of Residues of Linuron in Soybeans and Processed Products: Laboratory Project ID AMR-969-87. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. in cooperation with The National Food Laboratory, Inc. and Enviro-Bio-Tech. Ltd. 66 p.

41377601 Eble, J. (1989) Magnitude of Lorox L and Lorox DF Herbicide Residues in Sorghum: Lab Project Number: AMR/1131/88. Unpublished study prepared by Morse Laboratories. 47 p

41452601 Elbe, J. (1990) Magnitude of Lorox L and Lorox DF Herbicide Residues in Asparagus: Lab Project No: ML89-0125-DUP: AMR-1134-88. Unpublished study prepared by Morse Laboratories. 51 p.

41452701 Elbe, J. (1990) Magnitude of Lorox L Herbicide Residues in Potatoes: Lab Project Number: AMR-1132-88. Unpublished study prepared by Morse Laboratories. 47 p.

41501501 Eble, J. (1989) Magnitude of Lorox L and Lorox DF Herbicide Residues in Celery: Lab Project Number: AMR-1133-88. Unpublished study prepared by E. I. du Pont de Nemours & Co., Inc. 42 p.

41503401 Eble, J. (1990) Magnitude of Lorox L and Lorox DF Herbicide Residues in Cotton: Lab Project Number: AMR-1130-88. Unpublished study prepared by du Pont Agric. Products Dept., Glasgow Residue Lab. 47 p.

41569901 Eble, J. (1990) Magnitude of Lorox L and Lorox DF Herbicide Residues in Cotton: Lab Project Number: AMR-1130-88. Unpublished study prepared by E.I. du Pont de Nemours & Co. 47 p.

41716101 Brown, A. (1986) Supplement No. 1 to: Metabolism of [carbon 14] - Linuron by Potato Plants: Lab Project Number: AMR 559-86. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 20 p.

41716102 Brown, A. (1986) Supplement No. 1 to Metabolism of [carbon 14] - Linuron in Field-grown Soybean Plants: Lab Project Number: AMR 570-86. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 25 p.

41716103 E.I. du Pont de Nemours and Co. (1990) Supplement No. 1 to: Linuron Residue Study: Supplement: Response to Special Review/Reregistration Guidance Document-EPA Case No. 47 (6/29/84): Lab Project Number: 47. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 33 p.

41938101 Brown, A. (1991) Supplement #2 to: Metabolism of [Carbon 14] Linuron by Potato Plants (MRID 00164196): Lab Project Number: AMR 559-86. Unpublished study prepared by E.I. du Pont de Nemours and Co. 30 p.

42379901 McClory, J.; Tomic, D. (1992) Residues of Lorox Herbicide in Carrots as Affected by Cooking: Lab Project Number: 39

AMR 1701-90: ML91-0259-DUP. Unpublished study prepared by E. I. du Pont de Nemours and Comp., Morse Laboratories. 81 p.

42397201 McClory, J.; Tomic, D. (1992) Residues of Lorox Herbicide in Potatoes and their Processed Fractions: Lab Project Number: AMR 1698-90: 65388-01: ML90-0211-DUP. Unpublished study prepared by E. I. du Pont de Nemours and Co., Arthur D. Little, Inc., and Others. 180 p.

42462901 McClory, J.; Jones, W.; Sund, R. et al. (1992) Residues of Lorox Herbicide in Soybeans and Its Processed Fractions: Lab Project Number: AMR 1699-90. Unpublished study prepared by E. I. du Pont de Nemours and Co. in cooperation with The Texas A&M University System. 68 p.

42462902 McClory, J.; Tomic, D. (1992) Residues of Lorox Herbicide in Asparaggus as Affected by Cooking: Lab Project Number: AMR 1700-90: ML90-0258-DUP. Unpublished study prepared by E. I. du Pont de Nemours and Co. in cooperation with Morse Laboratories, Inc. 70 p.

42542101 Brown, A. (1992) Plant Metabolism Study of [Phenyl(U)-carbon 14] Linuron in Potatoes: Lab Project Number: AMR 2236-91. Unpublished study prepared by E.I. du Pont de Nemours and Company. 53 p.

42542102 McClory, J.; Devine, P. (1992) Residues of Lorox Herbicide in Grain Sorghum Seed and Its Processed Fractions: Lab Project Number: AMR 1918-91: LOR-1918-91: ML92-0324-DUP. Unpublished study prepared by E.I. du Pont de Nemours and Company, Texas A&M, and Morse Labs, Inc. 88 p.

42548401 Brown, A. (1992) Plant Metabolism Study of [Phenyl(U)-carbon 14] Linuron in Soybeans: Lab Project Number: AMR 2159-91. Unpublished study prepared by E.I. du Pont de Nemours and Co. 60 p.

42560001 McClory, J.; Tomic, D. (1992) Residues of Lorox Herbicide in Field Corn Grain and its Processed Fractions: Lab Project Number: AMR 1916-91: LOR-1916-91: ML92-0294-DUP. Unpublished study prepared by E.I. DuPont de Nemours and Co. 116 p.

42605901 McClory, J.; Tomic, D. (1992) Residues of Linuron in Wheat and Wheat Straw Following Application of Lorox DF Herbicide: Lab Project Number: AMR 2136-92: LOR-2136-92. Unpublished study prepared by E. I. du Pont de Nemours and Co. and The Texas A &M University System. 59 p.

42635401 Hawkins, D.; Elsom, L.; Dighton, M.; et al. (1993) The Metabolism of (carbon 14)-Linuron in Laying Hens: Lab Project Number: HRC/DPT 267/921558: AMR-2200-91. Unpublished study prepared by Huntingdon Research Centre Ltd. 101 p.

42836701 McClory, J.; Jones, W.; Tomic, D. (1993) Freezer Storage Stability of Linuron on Fresh and Cooked Asparagus: Lab Project Number: AMR 2339-92. Unpublished study prepared by DuPont 40

Agricultural Products. 44 p.

42836702 McClory, J.; Jones, W.; Tomic, D. (1993) Freezer Storage Stability of Linuron on Wheat Straw and Grain: Lab Project Number: AMR 2623-93. Unpublished study prepared by DuPont Agricultural Products. 40 p.

PRODUCT CHEMISTRY CITATIONS

00162140 Industria Prodotti Chimici S.p.A. (1986) Linuron ~~Technical: Product Chemistry Data.~~ Unpublished compilation. 202 p.

40484501 Fanelli, R. (1987) Analysis of Trace Amounts of Chlorinated Dibenzo-dioxins and Chlorinated Dibenzo-furans in Samples of Technical Linuron. Unpublished compilation prepared by Instituto di Ricerche Farmacologiche "Mario Negri". 18 p.

41817201 Fanelli, R. (1991) Quantitative Analysis of Chlorinated Dibenzodioxins and Chlorinated Dibenzo-furans in Samples of Technical Linuron: Lab Project Number: 11/90. Unpublished study prepared by Instituto di Ricerche Farmacologiche "Mario Negri". 111 p.

41976501 Steiner, A. (1990) Linuron Technical: Product Chemistry: Lab Project Number: LINU/PCH 26. Unpublished study prepared by Agan Chemical Manufactures, Ltd. 133 p.

41976502 Castles, M. (1990) Determination of TCAB, TCAOB, and TCB in Technical Grade Linuron for Product Chemistry Portion of EPA Registration: Lab Project Number: LINU/PCH-25: 9676-A. Unpublished study prepared by Midwest Research Institute. 25 p.

42213301 Hogg, A. (1992) Linuron: Determination of Physico-Chemical Properties: Lab Project Number: 8/100/A. Unpublished study prepared by Safepharm Laboratories Ltd. 47 p.

42213302 Hogg, A. (1992) Linuron: Determination of Dissociation Constant and Partition Coefficient: Lab Project Number: 8/100/B. Unpublished study prepared by Safephram Labs., Ltd. 17 p.

42213303 Taylor, N. (1992) Linuron: Determination of Vapor Pressure by Balance Method: Lab Project Number: 114308. Unpublished study prepared by Univ. of Leeds. 34 p.

42347701 Industria Prodotti Chimici SpA. (1992) Linuron Technical - Product Chemistry: Preliminary Analysis and Certification of Ingredients: Lab Project Number: 944. Unpublished study. 118 p.

42347702 Fanelli, R. (1992) Confirmation of the Presence and Concentration of 2,3,7,8 TCDF in Technical Linuron (Third Report): Supplement to. Unpublished study prepared by Instituto di Ricerche Farmacologiche "Mario Negri". 11 p.

42347703 Bresnahan, J. (1992) Formal Report of Analysis for 41

N-Nitroso Compounds: Lab Project Number: 5450-7697. Unpublished study prepared by ThermedeTec, Inc. 179 p.

42493101 I.pi.ci. Industria Prodotti Chimici SpA. (1992) Linuron Technical Product Chemistry - Certified Limits: Lab Project Number: 944. Unpublished study prepared by I.pi.ci. Analytical Laboratory. 9 p.

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PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

ADDENDIX
Case No. 0047
Chemical No. 035506

Case Name: Linuron
Registrant: E.I. du Pont de Nemours and Company, Inc.
Product(s): 92% T (EPA Reg. No. 352-326[redacted]

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number [b]
61-1	Product Identity and Disclosure of Ingredients	N [c]	41976501
61-2	Starting Materials and Manufacturing Process	N [d]	41976501
61-3	Discussion of Formation of Impurities	N [e]	41976501
62-1	Preliminary Analysis	N [f]	41976501 41976502
62-2	Certification of Ingredient Limits	N [g]	41976501
62-3	Analytical Methods to Verify the Certified Limits	N [h]	41976501
63-2	Color	Y	**42213301**
63-3	Physical State	Y	**42213301**
63-4	Odor	Y	**42213301**
63-5	Melting Point	Y	**42213301**
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	**42213301**
63-8	Solubility	Y	**42213301**
63-9	Vapor Pressure	Y	**42213303**
63-10	Dissociation Constant	Y	**42213302**
63-11	Octanol/Water Partition Coefficient	Y	**42213302**
63-12	pH	Y	**42213301**
63-13	Stability	Y	**42213301** No MRID
63-14	Oxidizing or Reducing Action	Y	**42213301**
63-15	Flammability	N/A	
63-16	Explodability	N	
63-17	Storage Stability	N	
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	N	

[a] Y = Yes; N = No; N/A = Not Applicable.

[b] Bolded citations were reviewed under CBRS Nos. 9527 and 9458, D175278 and D174861, dated 7/16/92, by E. Zager; underlined citations were reviewed under CBRS No. 8489, D167782, dated 8/19/92, by R. Perfetti; remaining citation (No MRID) was reviewed under CBRS No. 10913, D184790, dated 12/30/92, by D. McNeilly.

[c] These data do not fully satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) concerning product identity because (i) two impurities listed on the CSF must be correctly identified; (ii) one component must be further characterized; (iii) the nominal concentrations of the impurities listed on the CSF must be reconciled with the results of preliminary analysis; (iv) two impurities listed on the CSF that are pesticidally active must be identified as active ingredients and included in the label claim; and (v) the label claim must be revised to reflect the nominal concentration of the active ingredient rather than the lower certified limit as per PR Notice 91-2 dated 5/2/91. In addition, we note that as per 40 CFR §152.43, this product may not meet the criteria of an alternate formulation because the certified limits for the active ingredient are not the same as those for the basic formulation.

[d] These data do not fully satisfy the requirements of 40 CFR §158.160 and 162 (Guideline Reference No. 61-2) concerning starting materials and the manufacturing process because the registrant must provide (i) information concerning the producers and specifications of two starting materials; (ii) the duration of each step and of the entire process; and (iii) a description of any purification measures (including procedures to recover or recycle starting materials, intermediates, or the substance produced).

[e] These data do not fully satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) concerning discussion of formation of impurities because the registrant must account for the presence of several impurities listed on the CSF, including tetrachloroazobenzene (TCAB), tetrachloroazoxybenzene (TCAOB), and tetrachlorobiphenyl (TCB), among others. In addition, the registrant must include a complete discussion of the following potential sources of impurities: (i) carryover of starting materials and impurities present or believed to be present in the starting materials; (ii) the degradation of ingredients in the product after its production, but prior to use; (iii) post-production reactions between the ingredients in the product; (iv) migration of packing components into the product; and (v) carryover of contaminants from use of the manufacturing equipment for other products. Finally, because linuron is a secondary alkylamine, the registrant must discuss the potential for formation of nitrosamines.

[f] These data do not fully satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) concerning preliminary analysis because preliminary analysis for nitrosamines must be submitted. In addition, complete validation data must be submitted to support the methods used to determine several organic impurities listed on the CSF and the microcontaminants TCAB, TCAOB, and TCB. Finally, one component should be further analyzed since it may contain an EPA List 2 inert.

[g] These data do not fully satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) concerning certified limits because the upper certified limits proposed for the impurities do not reflect the results of the preliminary analysis; the registrant must explain the basis for the determination of

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the certified limits.

[a] These data do not fully satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) concerning enforcement analytical methods because the registrant must provide an enforcement method for the impurities TCAB, TCAOB, or TCB. We note that the HRGC/MS method used for preliminary analysis may not be suitable as an enforcement method, even if adequate validation data are submitted, because it requires the use of materials that are not readily available. Subdivision D of the Pesticide Assessment Guidelines requires that an enforcement analytical method be as simple, quick, and inexpensive to perform as possible. Finally, if several organic impurities which were listed as nondetectable in preliminary analysis are to be included on the CSF, adequately validated enforcement methods to determine these impurities must be submitted.

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PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

Case No. 0047
Chemical No. 035506

Case Name: Linuron
Registrant: E. I. du Pont de Nemours and Company, Inc. [redacted]
Product(s): 92% T (EPA Reg. No. 352-326) [redacted]

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number [b]
61-1	Product Identity and Disclosure of Ingredients	N [c]	00162140 CSF dated 6/18/92
61-2	Beginning Materials and Manufacturing Process	Y	00162140
61-3	Discussion of Formation of Impurities	Y	00162140
62-1	Preliminary Analysis	Y	00162140 40484501 [d] 41817201 [e] 42347701 42347702 42347703
62-2	Certification of Ingredient Limits	Y [f]	CSF dated 6/18/92 42493101 [g]
62-3	Analytical Methods to Verify the Certified Limits	Y	00162140
63-2	Color	Y	00162140
63-3	Physical State	Y	00162140
63-4	Odor	Y	00162140
63-5	Melting Point	Y	00162140
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	00162140
63-8	Solubility	Y	00162140
63-9	Vapor Pressure	Y	00162140
63-10	Dissociation Constant	Y	00162140
63-11	Octanol/Water Partition Coefficient	Y	00162140
63-12	pH	Y	00162140
63-13	Stability	Y	00162140
63-14	Oxidizing or Reducing Action	Y	00162140
63-15	Flammability	N/A	
63-16	Explodability	Y	00162140
63-17	Storage Stability	Y	00162140
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	Y	00162140

[a] Y = Yes; N = No; N/A = Not Applicable.

[b] Bolded citations were reviewed under CBRS No. 1318, dated 10/28/86, by J. Garbus in connection with data review for Aceto Corp.; underlined citations were reviewed under CBRS Nos. 10034 and 10138, D179497 and D179989, dated 8/25/92 by R. Perfetti; remaining citations were reviewed as noted.

[c] These data do not fully satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) concerning product identity because the registrant must submit the nominal concentrations of the active ingredient and impurities. In addition, we note that one impurity present at $\leq$0.1% is pesticidally active.

[d] CBRS No. 3351, dated 1/13/89, by M. Flood.

[e] CBRS No. 7799, D163010, dated 7/24/91, by S. Funk.

[f] Certified limits must be submitted on EPA Form 8570-4 (Rev. 12/90), including an upper certified limit for [redacted] which was previously listed on the CSF.

[g] CBRS No. 11363, D187969, dated 6/29/93, by D. McNeilly.

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Case No. 0047
Chemical No. 035506

Case Name: Linuron
Registrant: Griffin Corporation
Product(s): 95% T (EPA Reg. No. 31812-270)[redacted]

Du Pont has submitted an agreement that data submitted for the du Pont alternate linuron formulation [redacted] may be used to support the Griffin linuron formulation [redacted] Therefore, the data requirements outlined in the Product Chemistry Data Summary table for the du Pont 95% T [redacted] also apply to the Griffin 95% T [redacted] Griffin must submit its own Confidential Statement of Formula including information concerning the registrant, registration number, producer, components by chemical name and their purposes, nominal concentrations, and certified limits.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

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Case No. 0047
Chemical No. 035506

Case Name: Linuron
Registrant: Drexel Chemical Company
Product(s): 95% Ts (EPA Reg. Nos. 19713-158, 19713-367, and 19713-368) produced by "undetermined" sources.

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number
61-1	Product Identity and Disclosure of Ingredients	N	
61-2	Starting Materials and Manufacturing Process	N	
61-3	Discussion of Formation of Impurities	N	
62-1	Preliminary Analysis	N	
62-2	Certification of Ingredient Limits	N	
62-3	Analytical Methods to Verify the Certified Limits	N	
63-2	Color	N	
63-3	Physical State	N	
63-4	Odor	N	
63-5	Melting Point	N	
63-6	Boiling Point	N	
63-7	Density, Bulk Density or Specific Gravity	N	
63-8	Solubility	N	
63-9	Vapor Pressure	N	
63-10	Dissociation Constant	N	
63-11	Octanol/Water Partition Coefficient	N	
63-12	pH	N	
63-13	Stability	N	
63-14	Oxidizing or Reducing Action	N	
63-15	Flammability	N	
63-16	Explodability	N	
63-17	Storage Stability	N	
63-18	Viscosity	N	
63-19	Miscibility	N	
63-20	Corrosion Characteristics	N	

[a] Y = Yes; N = No; N/A = Not Applicable. Until the sources of the Drexel linuron technical products are identified, CBRS cannot summarize the supporting database.

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